

SEP 20 2004

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510(K) SUMMARY

Submitter's Name, Address and Date of Submission

Robert W. Johnson
Vice President, Regulatory Affairs and Quality Assurance
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, MN 55110

Phone: 651-653-8512

Fax: 651-407-1975

Submitted: August 25, 2004

Device Name

Trade Name: BiomarC® Preloaded Tissue Marker Device

Classification Name: Implantable Staple, 21 CFR 878.4750
Implantable Clip, 21 CFR 878.4300

Common/Usual Name: Tissue Marker

Predicate Device

Promex Biopsy Site Tissue Marker Device (k)023450
BiomarC Tissue Marker (k) 032347

Indication for Use

BiomarC Preloaded Tissue Marker Device is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Device Description

The BiomarC Preloaded Tissue Marker Device is a sterile, nonpyrogenic, single use delivery system incorporating the BiomarC tissue marker consisting of a non-absorbable pyrolytic carbon coated zirconium oxide marker that is clearly visible on standard radiographs as well as Magnetic Resonance Imaging (MRI) and ultrasound. The BiomarC Tissue Marker is delivered either with an obturator or with the BiomarC Delivery Gel. BiomarC is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a location.

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510(k) SUMMARY (CONTINUED)

Technological Characteristics and Performance

The technological characteristics are equivalent to the predicate device. Bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 20 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert W. Johnson
Vice President, Regulatory Affairs
and Quality Assurance
Carbon Medical Technologies, Inc,
1290 Hammond Road
Saint Paul, Minnesota 55110

Re: K042296
Trade/Device Name: BiomarC® Preloaded Tissue Marker Device
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU, GDW
Dated: August 24, 2004
Received: August 24, 2004

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K042296

Indications for Use Statement

510(k) Number (if known) _____

Device Name **BiomarC® Preloaded Tissue Marker Device**

Indications for Use

The BiomarC Preloaded Tissue Marker Device is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

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